

### **REMARKS/ARGUMENTS**

Claims 50 and 75 are amended by this response. No claims are canceled or added. Accordingly, following entry of this response, claims 50-77 will remain pending.

#### **Rejection of Claims Under 35 U.S.C. §101 for Purported Lack of Utility**

Claims 50-77 are rejected under 35 U.S.C. §101 based upon a purported lack of patentable utility. These claim rejections are overcome as follows.

Guidelines for determining compliance with the Utility requirement are set forth in the Manual of Patent Examining Procedure (MPEP) at §2107(II)(B)(1):

If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a “specific and substantial utility”) and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility. (Emphasis added)

Here, the Examiner explicitly concedes that the instant specification:

does disclose that there is a need in the art for systems for modeling the behavior of drug candidates wherein different knowledge is used for developing a model of compound's clinical safety, tolerability, and efficacy profile in relation to the compounds' competitors. (Emphasis added; Office Action Mailed November 29, 2006, page 4, lines 2-5)

Each of the pending independent claims 50 and 75 is now accordingly amended to incorporate this utility recognized by the Examiner.

In view of the Examiner's express acknowledgment of the utility of the function now recited in each of the pending independent claims, there can be no question that Applicants have clearly met the burden imposed by the Examination Guidelines set forth in MPEP §2107. Continued rejection of the claims as lacking utility is accordingly improper, and these claim rejections should be withdrawn.

#### **Rejection of Claims Under 35 U.S.C. §112 ¶1 For Purported Lack of Enablement**

Claims 50-77 were also rejected under 35 U.S.C. §112 ¶1 for lack of enablement, based upon their purported lack of utility. As described above, the pending claims have now been amended to overcome the lack of utility rejection. Accordingly, it is understood that the non-

enablement claim rejections have been overcome as well, and the Examiner is respectfully requested to withdraw these claim rejections.

### **Rejection of Claims Under 35 U.S.C. §112 ¶2 For Purported Indefiniteness**

Claims 50-77 are rejected under 35 U.S.C. §112 ¶2 for purportedly failing to particularly point out and distinctly claim subject matter which Applicants regard as the invention. Specifically, in the latest office action the Examiner cites a litany of claim terms that she feels to be indefinite.

As a threshold matter, Applicants note that the Examiner appears to be placing undue emphasis on technical, non-prior art rejections:

#### **706.03 Rejections Not Based on Prior Art**

The primary object of the examination of an application is to determine whether or not the claims are patentable over the prior art. This consideration should not be relegated to a secondary position while undue emphasis is given to nonprior art or “technical” rejections. Effort in examining should be concentrated on truly essential matters, minimizing or eliminating effort on technical rejections which are not really critical. (Emphasis added)

Here, the Examiner is respectfully reminded that Applicants are afforded a wide latitude in their choice of claim terminology:

A fundamental principle contained in 35 U.S.C. §112, ¶2 is that applicants are their own lexicographers. . . . Applicant may use functional language, alternative expressions, negative limitations, or any style of expression or format of claim . . . . (Emphasis added; MPEP §2173.01)

Moreover, the MPEP directs the Examiner to:

allow claims which define the patentable subject matter with a reasonable degree of particularity and distinctness. Some latitude in the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. (Emphasis original; MPEP §2173.02)

The following TABLE lists terms the Examiner alleges to be indefinite, and provides the corresponding location in the specification of text describing those terms:

TABLE (all emphasis added)

Claim Term	Location of Description in Specification
raw data generated by a model	<p><b>Figure 9;</b> "After developing a model, modeling expert 900 uses it to run simulations producing a collection of files 902 comprising <u>raw simulation output data</u>." (§[0103])</p> <p><b>Figure 10B;</b> "left half 1000 of Figure 10B represents <u>raw simulation output by a model</u> in an arbitrary format that only implicitly reflects the hierarchical structure of the model." (§[0120])</p>
explicitly referencing a hierarchical structure model	<p><b>Figure 9;</b> "Metadata file 906 encodes a hierarchical structure of the model (i.e. the outputs and related inputs) that is implicit in the structure of the raw simulation files 902." (§[0105]) "Binary file 912 is <u>organized to match the structure</u> encoded in the metadata file 906." (§[0108])</p> <p><b>Figure 10B;</b> "right half 1002 of Figure 10B represents the same data organized into the DMX format <u>explicitly encoded to reflect the hierarchical structure of the model</u>." (§[0120])</p>
referencing index information and metadata	<p><b>Figure 9;</b> "Metadata file 906 encodes a hierarchical structure of the model (i.e. the outputs and related inputs) that is implicit in the structure of the raw simulation files 902. This encoding is defined within the Metadata file <u>in terms of labels used in the raw simulation output files</u>." (§[0105])</p> <p><b>Figure 10B;</b> "metadata file 1016 is a replacement for the simulation index file 1004. Index information contained in files 1004 and 1012 is extracted and utilized to encode the metadata file 1016." (§[0124])</p>
generate a metadata file	<p><b>Figure 9;</b> Parser module 904 reads files 902 and produces two separate output files 906 and 908. The first file output by DMX Parser Module 904 <u>is the Metadata file 906</u>." (§[0105])</p> <p><b>Figure 10B;</b> Software routines of the DMX data conversion modules 1014 receive files 1004 and 1012 as inputs, parses them, producing as output two new files 1016 and 1018. . . . The DMX <u>metadata file 1016</u> is a replacement for the simulation index file 1004. (§[0124]-[0124])</p>
referencing metadata to convert the raw data	<p><b>Figure 9;</b> "Data transfer module 910 comprises software which <u>converts the multiple raw simulation output files into a single binary file 912</u>. Binary file 912 is organized to match the structure encoded in the metadata file 906." (§[0108]-[0109])</p> <p><b>Figure 10B;</b> "Data contained in the original output file 1012 <u>is converted in binary file 1018</u> into an n-dimensional hypercube structure. The geometry of this structure matches the tree structure of metadata file 1016." (§[0125])</p>
identifying locations of treatment scenario information types	<p><b>Figure 10B;</b> "structure of DMX data files 1016 and 1018 reveals that taken together, they <u>locate treatment types</u> and corresponding simulated results in a manner which explicitly reflects the hierarchical structure of the original model. Specifically, in this conceptual example limited to 3 dimensions for the convenience of communication, binary file 1018 comprises a structure having X-, Y-, and Z- axes corresponding to each of the input variables." (§[0124])</p>

The description of the above claim terms in the specification may not be as precise as the Examiner might desire. However, as amply evidenced above, these claim terms are discussed in

the specification in connection with both Figures 9 and 10B. Such disclosure certainly provides the reasonable degree of particularity and distinctness called for by the MPEP. Accordingly, continued maintenance of the indefiniteness claim rejections is improper, and the claim rejections should be withdrawn.

Finally, in a previous office action the Examiner indicated some uncertainty as to whether the following recited steps are active method steps: "referencing of index information", generating the metadata file, converting the raw data, and identifying a subset. Applicants previously responded, and reiterate again now, that all steps cited by the Examiner are indeed affirmatively recited elements of the claimed embodiments.

#### **Rejection of Claims Based Upon Purported Prior Art**

All pending claims stand rejected as obvious in view of either U.S. patent no. 5,808,918 to Fink ("the Fink Patent"), or U.S. patent no. 6,108,635 to Herren et al. ("the Herren Patent"), taken in combination with other references. These claim rejections are traversed as follows.

A first requirement to establish a prima facie case of obviousness is that "the prior art reference (or references when combined) must teach or suggest all of the claim limitations." (MPEP 2143).

Here, the Examiner openly concedes that that neither the Fink Patent nor the Watkins Patent, teaches or suggests converting raw data into a binary file by referencing a metadata file. (See Office Action Mailed November 29, 2006 at page 10, lines 6-7, and page 13, lines 19-20)

To provide this missing teaching, the Examiner has combined either the Fink Patent or the Herren Patent with U.S. patent no. 6,457,017 to Watkins et al. ("the Watkins Patent").

However, the Examiner is respectfully reminded that in order to establish a prima facie case of obviousness:

there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. (MPEP 2143).

Such teaching or suggestion to make the claimed combination must be found in the prior art, not in applicant's own disclosure. In re Vaeck, 947 F.2d 488 (Fed.Cir. 1991).

Here, there is absolutely no teaching in the Fink Patent to motivate its combination with the Watkins Patent.

For example, as shown in Figure 3 (reproduced below), the Fink Patent describes a system in which a hierarchical model structure is reflected in the user interface:

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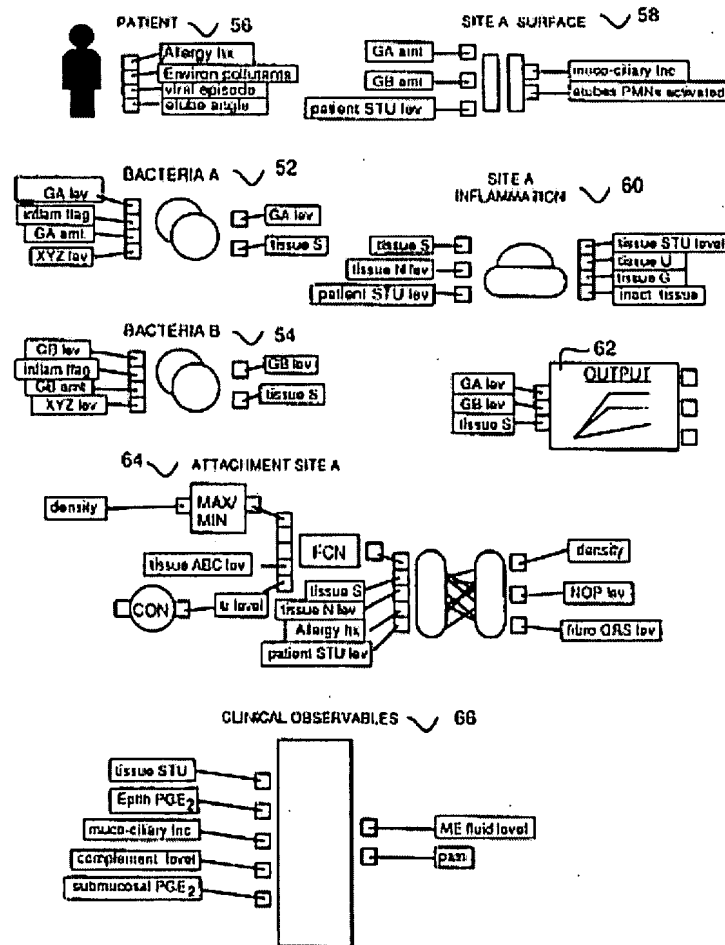


FIG. 3 is a block diagram showing a typical display and structure 68 of the entities making up the highest level of the model. . . . the drawings in the present specification only convey information regarding making and using a hierarchical biological model, and are not intended to be biologically precise. (Emphasis added; col. 5, lines 39-47)

Figures 4 and 5 of the Fink Patent go on to show additional user interfaces representing the hierarchical structure of the model:

FIG. 4 is a block diagram showing an interactive display and structure 94 of the level of the hierarchy below the level shown in FIG. 3. (Emphasis added; col. 6, lines 24-26)

\* \* \*

FIG. 5 is an example of an interactive display and structure 102 of another level of the hierarchy of a cell pool. (Emphasis added; col. 6, lines 41-42)

The Fink Patent thus already teaches a user interface that reflects a hierarchical structure of a model. Where is the Examiner finding motivation to combine this reference with another (the Watkins Patent) involving creation of metadata and binary files?

The instant application provides ample teaching regarding generation of a metadata file reflecting hierarchical model structure. However, the Examiner is respectfully reminded that any suggestion to combine references must be found in the prior art, and not be based upon applicants' own disclosure:

The tendency to resort to "hindsight" based upon applicant's disclosure is often difficult to avoid due to the very nature of the examination process. However, impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art. (Emphasis added; MPEP 2142)

Because the Fink Patent already teaches a user interface reflecting a hierarchical structure of a model, there is thus absolutely no motivation to combine this reference with the Watkins Patent relied upon by the Examiner. Moreover, resort by the Examiner to Applicants' own disclosure to provide motivation or suggestion for combination is strictly prohibited as impermissible hindsight. And as such, the instant obviousness rejections are improper and should be withdrawn.

Finally, the Examiner alternatively rejected the claims as obvious based upon the Herren Patent in combination with the Watkins Patent. Again, however, Applicants can discern no legitimate motivation for combining these references.

The Herren Patent describes modeling of complex biological systems. By contrast, the Watkins Patent discloses a document management system, and contains no mention whatsoever regarding manipulation of raw data of the type expected to be output from a complex model.

The Examiner is respectfully reminded that the combination of elements from nonanalogous sources in a manner that produces the invention only with the benefit of hindsight,

is an insufficient basis for a conclusion of nonobviousness. In re Oetiker, 977 F.2d 1443 (Fed.Cir. 1992). To guard against the tempting trap of hindsight, the evidence of a suggestion, teaching, or motivation to combine "must be clear and particular." In re Dembiczak, 50 U.S.P.Q.2d, 1614, 1617 (Fed.Cir. 1999) (citation omitted).


Here, the Examiner simply asserts that the motivation for combining the Herren and Watkins Patents "would have been to improve selecting and viewing data". (Office Action mailed November 29, 2006, page 14, lines 14-15)

However, the complex biological "data" output by the model of the Herren Patent, is a far cry from the "data" allowing management of documents under the system disclosed by the Watkins Patent. There is no legitimate basis for combining these references, and Applicants respectfully assert that the Examiner has instead simply pieced together distinct teachings of multiple nonanalogous references based on the present disclosure.

In conclusion, just because the two components or techniques can conceivably be used together, does not constitute evidence of a motivation to combine them. "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight." In re Dembiczak (citing Interconnect Planning Corp. v. Feil, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985)).

Based at least upon the failure of the references relied upon by the Examiner to provide motivation for their combination, it is respectfully asserted that the pending claims cannot be considered obvious. Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

  
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